ARC 4899C

HUMAN SERVICES DEPARTMENT[441]

Adopted and Filed

Rule making related to medical and remedial services

The Human Services Department hereby amends Chapter 78, "Amount, Duration and Scope of Medical and Remedial Services," and Chapter 79, "Other Policies Relating to Providers of Medical and Remedial Care," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 249A.4.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 249A.4.

Purpose and Summary

This rule making updates and clarifies language to reflect existing prescribed outpatient drug policies for qualified prescribers, reasons for nonpayments of drugs, covered nonprescription drugs, quantity prescribed, drug reimbursement methodology (including dispensing fee limitation) and credits for returned unit dose drugs not consumed. This rule making also adds language regarding initiation of refill requirements with the prohibition of automatic refills without the member's consent and includes legislatively required prior authorization (PA) limitations on medication-assisted treatment (MAT), including opioid overdose treatment, under the pharmacy and medical benefits.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on November 20, 2019, as **ARC 4763C**.

The Department received seven comments from two respondents regarding the proposed changes: Flora A. Schmidt, Executive Director, Iowa Behavioral Health Association; and Casey Ficek, J.D., Director, Public Affairs, Iowa Pharmacy Association. The comments and corresponding responses from the Department are divided into five topic areas as follows:

1. Nonpayment of drugs. Two comments were received on this topic.

• One respondent commented that the rules, in not allowing payment for drug products administered in a practitioner's office, outpatient clinic or infusion center, may limit access to MAT drugs at opioid treatment programs, MAT unit sites and mental health centers and substance abuse treatment facilities. The respondent requested deletion of the provision or its amendment, with exceptions for behavioral health facilities.

• One respondent commented that not allowing payment for drug products administered in a practitioner's office, outpatient clinic or infusion center, while current policy under Medicaid, has resulted in some access issues for certain therapies provided in an infusion center controlled setting for Medicaid patients and requested reconsideration.

Department response: The Department will further research the access concerns identified in the comments before formalizing the policy in rule. The proposed statement has been removed from this adopted rule making.

2. Prior authorization for medication-assisted treatment drugs. Two comments were received on this topic.

• One respondent recommended a formatting change for the rule language and requested deletion of added language, indicating that it was not in the legislative language for this requirement.

Department response: The Department inserted a line break return after the last drug in the list in subrule 78.28(2). The language "opioid overdose agent" clarifies that naltrexone is approved by the Food and Drug Administration (FDA) for the treatment of opioid overdose. The Department revised the language to clarify concerns.

• One respondent expressed support for the removal of the prior authorization requirements to increase access to treatment for opioid use disorder.

Department response: The Department agrees with the comment. Increased access to treatment was the reason the Department initiated removal of the prior authorization requirement in the administrative rules.

3. Qualified prescriber. One comment was received on this topic.

• One respondent expressed support for the change to eliminate the list of specific qualified prescribers to ensure that the list will not have to be continually updated to reflect future changes in state law.

Department response: The Department agrees with the comment, and this was the reason the Department initiated removal of the prescriber list in the administrative rules.

4. Professional dispensing fee. One comment was received on this topic.

• One respondent expressed concerns about how one dispensing per month may affect patients seeking to utilize medication synchronization services, patients residing in nursing home and long-term care facilities, and prepacked drugs in less than a 30-day supply (for example, oral contraceptives).

Department response: Medication synchronization services are not a currently covered policy under Medicaid, and this rule language will not change that. If a pharmacy makes a business model decision to service nursing homes and long-term care facilities, that pharmacy has the ability to continue billing according to its existing process (for example, less than a month's supply). However, a dispensing fee will only be reimbursed once a month for maintenance drugs. Additionally, the pharmacy may choose to accumulate the billing to once a month as is the current process these pharmacies utilize for controlled substances. Lastly, the dispensing fee programming takes into account the monthly package size in allowing reimbursement of a dispensing fee in accordance with the refill tolerance of 90 percent consumption. Reimbursement of a dispensing fee would be allowed on a 28-day oral contraceptive when the refill is allowed on the 25th day. The Department updated the dispensing fee language in this rule making to account for the refill tolerance.

5. Unit dose packaging credits. One comment was received on this topic.

• A respondent commented that returns of unit dose packaging by a pharmacy must be consistent with Iowa Board of Pharmacy's rules and that the Department's rule language would result in pharmacies losing the cost of the medication returned and credited.

Department response: The Department agrees that a pharmacy must follow the Iowa Board of Pharmacy's rules on drug returns and has added that wording to these rules to clarify. This language is consistent with guidance in Informational Letter No. 497 released on April 21, 2006, and in the Prescribed Drugs Provider Manual.

Following review of the comments related to the proposed rule making, the Department has made the following changes from the Notice:

1. Removed proposed subparagraph 78.2(4)"b"(13), which would have prohibited payment for drug products administered in a practitioner's office, outpatient clinic or infusion center.

2. Revised new subrule 78.28(2) in Item 17 to include the clarifications described above. The subrule now reads as follows:

"**78.28(2)** Notwithstanding the provisions of 78.28(1)*"a,"* under both Medicaid fee-for-service and managed care administration, at least one form of each of the following drugs for medication-assisted treatment as approved by the United States Food and Drug Administration for treatment of substance use disorder or overdose treatment will be available without prior authorization:

"*a.* Buprenorphine,

"*b.* Buprenorphine and naloxone combination,

"*c.* Methadone,

"*d.* Naltrexone, and

"*e.* Naloxone.

"For the purpose of this subrule, "medication-assisted treatment" means the medically monitored use of certain substance use disorder medications in combination with treatment services."

3. Added clarifying language to subparagraph 79.1(8)"c"(2) and paragraph 79.1(8)"d" in Item 19. Specifically, the phrase "accounting for the refill tolerance of 90 percent consumption" was added to subparagraph 79.1(8)"c"(2), and the phrase "consistent with the Iowa board of pharmacy's rules on return of drugs" was added to paragraph 79.1(8)"d."

Adoption of Rule Making

This rule making was adopted by the Council on Human Services on January 8, 2020.

Fiscal Impact

Removal of clinical PA for MAT drugs is projected to have the following impacts:

- For the pharmacy benefit: It is estimated removing the PA requirement will result in additional expenditures for this category of drugs. There will be increased prescribing/utilization.
- Pharmacy benefit increased expenditures are estimated at the following: Total dollars before rebates $80,000 ($24,000 state share); $35,000 net of rebates ($10,500 state share). The state share is based on a blend between the traditional Medicaid and Iowa Health and Wellness Plan populations. This fiscal impact is a combined total for both fee-for-service (FFS) and managed care programs.
- There are no associated programming costs with this change.
- For the medical benefit: There is no fiscal impact as none of these drugs require a PA under the medical benefit.
- Medical contracts: No impact is projected to the medical contracts general fund appropriation.

Enforcement of the dispensing fee allowance on maintenance drugs is projected to have the following impacts:

- Clarifying the quantity prescribed and dispensing fee allowance could result in savings to the Medicaid program in cases where a pharmacy has been reimbursed greater than one dispensing fee per drug per member per month for maintenance drugs.
- The annualized savings are projected to be as follows per program based on the current dispensing fee of $10.07 and current utilization:
  - FFS $31,418 total (state and federal) dollars (based on April 2019 data and annualized).
  - Amerigroup $336,000 (based on April 2019 data and annualized).
  - UnitedHealthcare $660,965 (based on March 2019 data and annualized).

For both changes, PA removal and limit of one dispensing fee, the managed care organization (MCO) cost impact is part of the capitation rate setting.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to rule 441—1.8(17A,217).

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on March 18, 2020.

The following rule-making actions are adopted:

ITEM 1. Amend subrule 78.1(18) as follows:

78.1(18) Payment and procedure for obtaining eyeglasses, contact lenses, and visual aids, shall be the same as described in 441—78.6(249A). (Cross reference ~~78.28(3)~~ 78.28(4))

ITEM 2. Adopt the following **new** subrule 78.1(25):

78.1(25) Prior authorization for medication-assisted treatment shall be governed pursuant to subrule 78.28(2).

ITEM 3. Amend subrules 78.2(1) to 78.2(6) as follows:

78.2(1) *Qualified prescriber.* All drugs are covered only if prescribed by a legally qualified practitioner ~~(physician, dentist, podiatrist, optometrist, physician assistant, or advanced registered nurse practitioner)~~. Pursuant to Public Law 111-148, Section 6401, any practitioner prescribing drugs must be enrolled with the Iowa Medicaid enterprise in order for such prescribed drugs to be eligible for payment.

78.2(2) and **78.2(3)** No change.

78.2(4) *Prescription drugs.* Drugs that may be dispensed only upon a prescription are covered subject to the following limitations.

a. Prior authorization is required as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A ~~as amended by 2010 Iowa Acts, Senate File 2088, section 347~~.

(1) to (3) No change.

(4) Prior authorization for medication-assisted treatment shall be governed pursuant to subrule 78.28(2).

b. Payment is not made for:

(1) to (7) No change.

(8) Drugs prescribed for fertility purposes~~, except when prescribed for a medically accepted indication other than infertility, as defined in subparagraph (1)~~.

(9) to (12) No change.

78.2(5) *Nonprescription drugs.*

a. The following drugs that may otherwise be dispensed without a prescription are covered subject to the prior authorization requirements stated below and as specified in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A:

Acetaminophen tablets 325 mg, 500 mg
Acetaminophen elixir 160 mg/5 ml
Acetaminophen solution 100 mg/ml
Acetaminophen suppositories 120 mg
Artificial tears ophthalmic solution
Artificial tears ophthalmic ointment
Aspirin tablets 81 mg, chewable
Aspirin tablets 81 mg, 325 mg, and 650 mg~~, 81 mg (chewable)~~ oral
Aspirin tablets, enteric coated 325 mg, 650 mg, 81 mg
Aspirin tablets, buffered 325 mg
Bacitracin ointment 500 units/gm
Benzoyl peroxide 5%, gel, lotion
Benzoyl peroxide 10%, gel, lotion
~~Calcium carbonate chewable tablets 500 mg, 750 mg, 1000 mg, 1250 mg~~
~~Calcium carbonate suspension 1250 mg/5 ml~~
~~Calcium carbonate tablets 600 mg~~
~~Calcium carbonate-vitamin D tablets 500 mg-200 units~~
~~Calcium carbonate-vitamin D tablets 600 mg-200 units~~

~~Calcium citrate tablets 950 mg (200 mg elemental calcium)~~
~~Calcium gluconate tablets 650 mg~~
~~Calcium lactate tablets 650 mg~~
Cetirizine hydrochloride liquid 1 mg/ml
Cetirizine hydrochloride tablets 5 mg
Cetirizine hydrochloride tablets 10 mg
Chlorpheniramine maleate tablets 4 mg
Clotrimazole vaginal cream 1%
Diphenhydramine hydrochloride capsules 25 mg
Diphenhydramine hydrochloride elixir, liquid, and syrup 12.5 mg/5 ml
Epinephrine racemic solution 2.25%
Ferrous sulfate solution 75 mg/0.6 ml (15 mg/0.6 ml elemental iron)
Ferrous sulfate tablets 325 mg
Ferrous sulfate elixir 220 mg/5 ml
Ferrous sulfate drops 75 mg/0.6 ml
Ferrous gluconate tablets 325 mg
Ferrous fumarate tablets 325 mg
Guaifenesin 100 mg/5 ml with dextromethorphan 10 mg/5 ml liquid
Ibuprofen suspension 100 mg/5 ml
Ibuprofen tablets 200 mg
Insulin
Lactic acid (ammonium lactate) lotion 12%
Levonorgestrel 1.5 mg
Loperamide hydrochloride liquid 1 mg/5 ml
Loperamide hydrochloride liquid 1 mg/7.5 ml
Loperamide hydrochloride tablets 2 mg
Loratadine syrup 5 mg/5 ml
Loratadine tablets 10 mg
Magnesium hydroxide suspension 400 mg/5 ml
~~Magnesium oxide capsule 140 mg (85 mg elemental magnesium)~~
~~Magnesium oxide tablets 400 mg~~
Meclizine hydrochloride tablets 12.5 mg, 25 mg oral and chewable
Miconazole nitrate cream 2% topical and vaginal
Miconazole nitrate vaginal suppositories, 100 mg
~~Multiple vitamin and mineral~~ Mineral products with prior authorization
Neomycin-bacitracin-polymyxin ointment
~~Niacin (nicotinic acid) tablets 50 mg, 100 mg, 250 mg, 500 mg~~
Nicotine gum 2 mg, 4 mg
Nicotine lozenge 2 mg, 4 mg
Nicotine patch 7 mg/day, 14 mg/day and 21 mg/day
Pediatric oral electrolyte solutions
Permethrin lotion 1%
Polyethylene glycol 3350 powder
Pseudoephedrine hydrochloride tablets 30 mg, 60 mg
Pseudoephedrine hydrochloride liquid 30 mg/5 ml
Pyrethrins-piperonyl butoxide liquid 0.33-4%
Pyrethrins-piperonyl butoxide shampoo 0.3-3%
Pyrethrins-piperonyl butoxide shampoo 0.33-4%
Salicylic acid liquid 17%
Senna tablets 187 mg
Sennosides-docusate sodium tablets 8.6 mg-50 mg
Sennosides syrup 8.8 mg/5 ml

Sennosides tablets 8.6 mg
Sodium bicarbonate tablets 325 mg
Sodium bicarbonate tablets 650 mg
Sodium chloride hypertonic ophthalmic ointment 5%
Sodium chloride hypertonic ophthalmic solution 5%
Tolnaftate 1% cream, solution, powder
Vitamins, single and multiple with prior authorization
Other nonprescription drugs listed as preferred in the preferred drug list published by the department pursuant to Iowa Code section 249A.20A.

b. No change.

78.2(6) *Quantity prescribed ~~and dispensed~~.*

a. Quantity prescribed. When it is not therapeutically contraindicated, the legally qualified practitioner shall prescribe ~~a quantity~~ not less than a one-month supply of covered prescription and nonprescription medication ~~sufficient for up to a 31-day supply~~. ~~Oral contraceptives~~ Contraceptives may be prescribed in ~~90-day~~ three-month quantities.

~~*b. Oral solid forms of covered nonprescription items shall be prescribed and dispensed in a minimum quantity of 100 units per prescription or the currently available consumer package size except when dispensed via a unit-dose system.*~~

b. Prescription refills.

(1) Prescription refills shall be performed and recorded in a manner consistent with existent state and federal laws, rules and regulations.

(2) Automatic refills.

1. Automatic refills are not allowed. A request specific to each medication is required.

2. All prescription refills shall be initiated by a request at the time of each fill by the prescriber, Medicaid member or person acting as an agent of the member, based on continued medical necessity.

ITEM 4. Amend rule 441—78.3(249A), introductory paragraph, as follows:

441—78.3(249A) Inpatient hospital services. Payment for inpatient hospital admission is approved when it meets the criteria for inpatient hospital care as determined by the Iowa Medicaid enterprise. All cases are subject to random retrospective review and may be subject to a more intensive retrospective review if abuse is suspected. In addition, transfers, outliers, and readmissions within 31 days are subject to random review. Selected admissions and procedures are subject to a 100 percent review before the services are rendered. Medicaid payment for inpatient hospital admissions and continued stays are approved when the admissions and continued stays are determined to meet the criteria for inpatient hospital care. (Cross reference ~~78.28(5)~~ 78.28(6)) The criteria are available from the IME Medical Services Unit, 100 Army Post Road, Des Moines, Iowa 50315, or in local hospital utilization review offices. No payment will be made for waiver days.

ITEM 5. Amend subrule 78.3(18) as follows:

78.3(18) Preprocedure review by the IME medical services unit is required if hospitals are to be reimbursed for certain frequently performed surgical procedures as set forth under subrule 78.1(19). Preprocedure review is also required for other types of major surgical procedures, such as organ transplants. Criteria are available from the IME medical services unit. (Cross reference ~~78.28(5)~~ 78.28(6))

ITEM 6. Amend subrule 78.4(4) as follows:

78.4(4) *Periodontal services.* Payment may be made for the following periodontal services:

a. No change.

b. Periodontal scaling and root planing is payable once every 24 months when prior approval has been received. Prior approval shall be granted per quadrant when radiographs demonstrate subgingival calculus or loss of crestal bone and when the periodontal probe chart shows evidence of pocket depths of 4 mm or greater. (Cross reference ~~78.28(2)*"a"*(1)~~ 78.28(3)*"a"*(1))

c. No change.

d. Tissue grafts. Pedicle soft tissue graft, free soft tissue graft, and subepithelial connective tissue graft are payable services with prior approval. Authorization shall be granted when the amount of tissue loss is causing problems such as continued bone loss, chronic root sensitivity, complete loss of attached tissue, or difficulty maintaining adequate oral hygiene. (Cross reference ~~78.28(2)*"a"*(2)~~ 78.28(3)*"a"*(2))

e. Periodontal maintenance therapy requires prior authorization. Approval shall be granted for members who have completed periodontal scaling and root planing at least three months prior to the initial periodontal maintenance therapy and the periodontal probe chart shows evidence of pocket depths of 4 mm or greater. (Cross reference ~~78.28(2)*"a"*(3)~~ 78.28(3)*"a"*(3))

f. and *g.* No change.

ITEM 7. Amend subparagraph **78.4(5)"c"(2)** as follows:

(2) Correction of problems resulting from conventional treatment including gross underfilling, perforations, and canal blockages with restorative materials. (Cross reference ~~78.28(2)*"c"*~~ 78.28(3)*"c"*)

ITEM 8. Amend subrule 78.4(7) as follows:

78.4(7) *Prosthetic services.* Payment may be made for the following prosthetic services:

a. and *b.* No change.

c. A removable partial denture replacing posterior teeth including six months' postdelivery care when prior approval has been received. Approval shall be granted when the member has fewer than eight posterior teeth in occlusion, excluding third molars, or the member has a full denture in one arch and a partial denture replacing posterior teeth is required in the opposing arch to balance occlusion. When one removable partial denture brings eight posterior teeth in occlusion, no additional removable partial denture will be approved. Six months' postdelivery care is included in the reimbursement for the denture. (Cross reference ~~78.28(2)*"b"*(1)~~ 78.28(3)*"b"*(1))

d. A fixed partial denture (including an acid etch fixed partial denture) replacing anterior teeth when prior approval has been received. Approval shall be granted for members who:

(1) and (2) No change.

High noble or noble metals shall be approved only when the member is allergic to all other restorative materials. (Cross reference ~~78.28(2)*"b"*(2)~~ 78.28(3)*"b"*(2))

e. to *n.* No change.

ITEM 9. Amend paragraph **78.4(8)"a"** as follows:

a. Minor treatment to control harmful habits when prior approval has been received. Approval shall be granted when it is cost-effective to lessen the severity of a malformation such that extensive treatment is not required. (Cross reference ~~78.28(2)*"c"*~~ 78.28(3)*"c"*)

ITEM 10. Amend subrule 78.6(4) as follows:

78.6(4) *Prior authorization.* Prior authorization is required for the following:

a. to *d.* No change.

e. Approval for press-on prisms shall be granted for members whose vision cannot be adequately corrected with other covered prisms.

(Cross reference ~~78.28(3)~~ 78.28(4))

ITEM 11. Amend rule 441—78.7(249A), introductory paragraph, as follows:

441—78.7(249A) Opticians. Payment will be approved only for certain services and supplies provided by opticians when prescribed by a physician (MD or DO) or an optometrist. Payment and procedure for obtaining services and supplies shall be the same as described in rule 441—78.6(249A). (Cross reference ~~78.28(3)~~ 78.28(4))

ITEM 12. Amend subrule 78.9(10) as follows:

78.9(10) *Private duty nursing or personal care services for persons aged 20 and under.* Payment for private duty nursing or personal care services for persons aged 20 and under shall be approved if determined to be medically necessary. Payment shall be made on an hourly unit of service.

a. No change.

b. Requirements.

(1) Private duty nursing or personal care services shall be ordered in writing by a physician as evidenced by the physician's signature on the plan of care.

(2) Private duty nursing or personal care services shall be authorized by the department or the department's designated review agent prior to payment.

(3) Prior authorization shall be requested at the time of initial submission of the plan of care or at any time the plan of care is substantially amended and shall be renewed with the department or the department's designated review agent. Initial request for and request for renewal of prior authorization shall be submitted to the department's designated review agent. The provider of the service is responsible for requesting prior authorization and for obtaining renewal of prior authorization.

The request for prior authorization shall include a nursing assessment, the plan of care, and supporting documentation. The request for prior authorization shall include all items previously identified as required treatment plan information and shall further include: any planned surgical interventions and projected time frame; information regarding caregiver's desire to become involved in the member's care, to adhere to program objectives, to work toward treatment plan goals, and to work toward maximum independence; and identify the types and service delivery levels of all other services to the member whether or not the services are reimbursable by Medicaid. Providers shall indicate the expected number of private duty nursing RN hours, private duty nursing LPN hours, or home health aide hours per day, the number of days per week, and the number of weeks or months of service per discipline. If the member is currently hospitalized, the projected date of discharge shall be included.

Prior authorization approvals shall not be granted for treatment plans that exceed 16 hours of home health agency services per day. (Cross reference ~~78.28(9)~~ 78.28(10))

ITEM 13. Amend subparagraph **78.10(3)"b"(10)** as follows:

(10) Vibrotactile aids. Vibrotactile aids are payable only once in a four-year period unless the original aid is broken beyond repair or lost. (Cross reference ~~78.28(4)~~ 78.28(5))

ITEM 14. Amend subparagraphs **78.14(7)"d"(1)** and **(2)** as follows:

(1) Payment for the replacement of a hearing aid less than four years old shall require prior approval except when the member is under 21 years of age. The department shall approve payment when the original hearing aid is lost or broken beyond repair or there is a significant change in the member's hearing that would require a different hearing aid. (Cross reference ~~78.28(4)*"a"*~~ 78.28(5)*"a"*)

(2) Payment for a hearing aid costing more than $650 shall require prior approval. The department shall approve payment for either of the following purposes (Cross reference ~~78.28(4)*"b"*~~ 78.28(5)*"b"*):

1. and 2. No change.

ITEM 15. Amend paragraph **78.26(4)"c"** as follows:

c. Preprocedure review by the IME medical services unit is required if ambulatory surgical centers are to be reimbursed for certain frequently performed surgical procedures as set forth under subrule 78.1(19). Criteria are available from the IME medical services unit. (Cross reference ~~78.28(6)~~ 78.28(7))

ITEM 16. Renumber subrules **78.28(2)** to **78.28(11)** as **78.28(3)** to **78.28(12)**.

ITEM 17. Adopt the following **new** subrule 78.28(2):

78.28(2) Notwithstanding the provisions of 78.28(1)*"a,"* under both Medicaid fee-for-service and managed care administration, at least one form of each of the following drugs for medication-assisted treatment as approved by the United States Food and Drug Administration for treatment of substance use disorder or overdose treatment will be available without prior authorization:

a. Buprenorphine,

b. Buprenorphine and naloxone combination,

c. Methadone,

d. Naltrexone, and

e. Naloxone.

For the purpose of this subrule, "medication-assisted treatment" means the medically monitored use of certain substance use disorder medications in combination with treatment services.

ITEM 18. Amend renumbered paragraphs **78.28(12)"a"** and **"b"** as follows:

a. Except as provided in paragraph ~~78.28(11)*"b,"*~~ 78.28(12)*"b,"* the following radiology procedures require prior approval:

(1) to (5) No change.

b. Notwithstanding paragraph ~~78.28(11)*"a,"*~~ 78.28(12)*"a,"* prior authorization is not required when any of the following applies:

(1) and (2) No change.

(3) The member received notice of retroactive Medicaid eligibility after receiving a radiology procedure at a time prior to the member's receipt of such notice (see paragraph ~~78.28(11)*"e"*~~ 78.28(12)*"e"*); or

(4) No change.

ITEM 19. Amend paragraphs **79.1(8)"a"** to **"g"** as follows:

a. Except as provided below in paragraphs 79.1(8)*"d"* through *"i,"* all providers are reimbursed for covered drugs as follows:

(1) Reimbursement for covered generic prescription drugs and for covered nonprescription drugs shall be the lowest of the following, as of the date of dispensing:

1. The average state actual acquisition cost (AAC), determined pursuant to paragraph 79.1(8)*"b,"* plus the professional dispensing fee determined pursuant to paragraph ~~79.1(8)*"c."*~~ 79.1(8)*"c"*;

2. The federal upper limit (FUL), defined as the upper limit for a multiple source drug established in accordance with the methodology of the Centers for Medicare and Medicaid Services as described in 42 CFR 447.514(a)-(c), plus the professional dispensing fee determined pursuant to paragraph ~~79.1(8)*"c."*~~ 79.1(8)*"c"*;

3. The total submitted charge~~.~~, represented by the lower of the gross amount due (GAD) as defined by the National Council for Prescription Drug Programs (NCPDP) standards definition, or the ingredient cost submitted plus the state defined professional dispensing fee, determined pursuant to paragraph 79.1(8)*"c"*; or

4. Providers' usual and customary charge to the general public.

(2) Reimbursement for covered brand-name prescription drugs shall be the lowest of the following, as of the date of dispensing:

1. The average state AAC, determined pursuant to paragraph 79.1(8)*"b,"* plus the professional dispensing fee determined pursuant to paragraph ~~79.1(8)*"c."*~~ 79.1(8)*"c"*;

2. The total submitted charge~~.~~, represented by the lower of the GAD as defined by the NCPDP standards definition, or the ingredient cost submitted plus the state defined professional dispensing fee; or

3. Providers' usual and customary charge to the general public.

b. No change.

c. Professional dispensing fee.

(1) For purposes of this subrule, the professional dispensing fee shall be a fee schedule amount determined by the department based on a survey of Iowa Medicaid participating pharmacy providers' costs of dispensing drugs to Medicaid beneficiaries. The survey shall be conducted every two years beginning in state fiscal year 2014-2015.

(2) There is a one-time professional dispensing fee reimbursed per one-month or three-month period, accounting for the refill tolerance of 90 percent consumption, per member, per drug, per strength, billed per provider for maintenance drugs as identified by MediSpan and maintenance nonprescription drugs.

d. For an oral solid dispensed to a patient in a nursing home in unit dose packaging prepared by the pharmacist, an additional one cent per dose shall be added to reimbursement based on acquisition cost or FUL. Payment may be made only for unit-dose-packaged drugs that are consumed by the patient. Any previous charges for unused unit-dose packages returned to the pharmacy must be credited to the Medicaid program, consistent with the Iowa board of pharmacy's rules on return of drugs.

e. 340B-purchased drugs.

(1) Notwithstanding paragraph 79.1(8)*"a"* above, reimbursement to a covered entity as defined in 42 U.S.C. 256b(a)(4) for covered outpatient drugs acquired by the entity through the 340B drug pricing program will be the lowest of:

1. The ~~submitted~~ 340B covered entity actual acquisition cost (not to exceed the 340B ceiling price), submitted in the ingredient cost field, plus the professional dispensing fee pursuant to paragraph 79.1(8)*"c"*;

2. The average state AAC determined pursuant to paragraph 79.1(8)*"b"* plus the professional dispensing fee pursuant to paragraph 79.1(8)*"c"*;

3. For generic prescription drugs and nonprescription drugs only, the FUL pursuant to 79.1(8)*"a"*(1)"2" plus the professional dispensing fee pursuant to paragraph 79.1(8)*"c"*;

4. The total submitted charge, represented by the GAD as defined by the NCPDP standards definition; or

5. Providers' usual and customary charge to the general public.

(2) Reimbursement for covered outpatient drugs to a 340B contract pharmacy, under contract with a covered entity described in 42 U.S.C. 256b(a)(4), will be according to paragraph 79.1(8)*"a"* because covered outpatient drugs purchased through the 340B drug pricing program cannot be billed to Medicaid by a 340B contract pharmacy.

f. Federal supply schedule (FSS) drugs. Notwithstanding paragraph 79.1(8)*"a"* above, reimbursement for drugs acquired by a provider through the FSS program managed by the federal General Services Administration will be the lowest of:

(1) The provider's actual acquisition cost~~,~~ (not to exceed the FSS price), submitted in the ingredient cost field, plus the professional dispensing fee pursuant to paragraph 79.1(8)*"c"*;

(2) The average state AAC determined pursuant to paragraph 79.1(8)*"b"* plus the professional dispensing fee pursuant to paragraph 79.1(8)*"c"*;

(3) For generic prescription drugs and nonprescription drugs only, the FUL pursuant to 79.1(8)*"a"*(1)"2" plus the professional dispensing fee pursuant to paragraph 79.1(8)*"c";*

(4) The total submitted charge, represented by the GAD as defined by the NCPDP standards definition; or

(5) Providers' usual and customary charge to the general public.

g. Nominal-price drugs. Notwithstanding paragraph 79.1(8)*"a"* above, reimbursement for drugs acquired by providers at nominal prices and excluded from the calculation of the drug's "best price" pursuant to 42 CFR 447.508 will be the lowest of:

(1) The provider's actual acquisition cost (not to exceed the nominal price paid), submitted in the ingredient cost field, plus the professional dispensing fee pursuant to paragraph 79.1(8)*"c"*;

(2) The average state AAC determined pursuant to paragraph 79.1(8)*"b"* plus the professional dispensing fee pursuant to paragraph 79.1(8)*"c"*;

(3) For generic prescription drugs and nonprescription drugs only, the FUL pursuant to 79.1(8)*"a"*(1)"2" plus the professional dispensing fee pursuant to paragraph 79.1(8)*"c"*;

(4) The total submitted charge, represented by the GAD as defined by the NCPDP standards definition; or

(5) Providers' usual and customary charge to the general public.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 2/12/20.